

Public Comment Summary Report

Project Title: A Patient-Reported Outcome Performance Measure (PRO-PM) Related to Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA).

Dates:

The Call for Public Comment ran from December 16th, 2020, to January 22nd, 2021.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Brigham and Women's Hospital (BWH) Center for Patient Safety Research and Practice to develop a new patient-reported outcome performance measure (PRO-PM) related to Care Goal Achievement following a total hip arthroplasty (THA) or total knee arthroplasty (TKA). The cooperative agreement name is Measuring Outcomes in Orthopedics Routinely (MOOR). The cooperative agreement number is 1V1CMS331637-01-00. As part of its measure development process, BWH requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

The project aim is to develop a new PRO-PM related to care goal achievement following THA or TKA that will assess the patient's main goals and expectations before surgery (i.e., pain, physical function and quality of life), and the degree to which the expectations were met or exceeded after surgery.

The primary objective of this project, as it relates to this public comment, is to gather stakeholder and expert input to inform quality measure development for patients undergoing elective primary THA or TKA. Specifically, in this public comment we sought feedback for the measure under development, a care goal achievement PRO-PM, in the following areas related to the measure specification:

- Measure Numerator Statement
- Measure Denominator Statement
- Inclusion and Exclusion Criteria

Information About the Comments Received:

The measure developer solicited public comments by posting on CMS' website and soliciting directly by email, with both options directing commenters to an online questionnaire hosted by Research Electronic Data Capture (REDCap); an online secure web platform used for data capture.

The survey asked closed ended questions about the measure specification and offered a free-text field for each question should the commenter want to provide more information. Importantly, while some of the stakeholders provided a detailed response to our questions, some of them only used the closed ended questions to express their agreement or disagreement with our measure specification description and statements.

We received ten responses on this topic. We were pleased to see that we had a wide variety of commenters respond who represented the areas of measure developers (n=3), medical associations

(n=1), healthcare leadership (n=2), surgeons (n=1), EHR vendors (n=2), and healthcare policy makers (n=1).

Stakeholder Comments

General Stakeholder Comments:

All of the commenters selected that in general, they found **overall value in our measure under development**, which aims to assess care goal achievement (i.e., goals and expectations) before and after total hip arthroplasty (THA) or total knee arthroplasty (TKA). Some commenters wrote in that having patient-reported outcome measures (PROMs) before and after surgery to measure patients' expectations and perceived outcomes was a good approach for assessing goal achievement, that the measure is important in improving patient's quality of care, and that the measure would improve communication among patients and providers. The measure was also seen as helpful for shared decision making.

While the following comments are not specific to the value of our measure under development, a couple of commenters posted in the general comment section wanting to understand the difference between the new care goal achievement measure and already established, validated clinical measures, such as the HOOS, KOOS, and PROMIS 10. It was also noted that the pre-surgical survey questions focused on patient expectations rather than patient goals.

Measure-Specific Stakeholder Comments:

Measure Numerator Statement

All of the commenters selected in the survey that they felt the **Measure Numerator Statement** best suits our measure under development. Overall, the measure numerator statement aligned with the measure as a relevant numerator and appears to show promise in assessing care goal achievement following THA or TKA procedures.

Most of the commenters selected in the survey that they did not feel there was any **Numerator Criteria to be Removed from or Applied** to our measure under development.

While no specific recommendations were made related to Measure Numerator Statement, a commenter did want to know if we considered patient, caregiver, and patient advocate feedback as part of the measure development process, as it was not clear from the information we provided. It was recommended that the care goal achievement criteria consider stakeholder feedback.

Measure Denominator Statement

All of the commenters selected in the survey that they felt the **Measure Denominator Statement** best suits our measure under development. Specifically, they thought that the measure denominator statement is well-designed and aligned with the measure. Alignment, reduction of patient burden, and harmonization among CMS MIPS measures is important and recommended.

It was recommended by one commenter that the care goal achievement pre- and post-surgical data collection periods be aligned with other measures developed (or being developed) and adopted by CMS for patient outcomes following primary elective THA or TKA for clinicians and clinician-groups (MIPS THA or TKA PRO-PM) to counter the additional burden to administer/complete/track responses at different timeframes. In addition, it was also recommended by the same commenter that because the items included in the developing surveys and the HOOS, JR and KOOS, JR contain overlapping concepts, an

explanation could be provided to patients and providers about the importance of completing these surveys.

There were language recommendations to ensure better comparability between hip patients and knee patients, i.e., change THA and/or TKA to THA or TKA.

One recommendation was made to change the pre-surgical data collection timeframe from 0-90 days to 0-60 days and from 90-180 days post-surgically to 60-180 days. Another recommendation was made to change the pre-surgical data collection timeframe from 0-90 days to 0-60 days and from 90-180 days post-surgically to 120-180 days. An alternative recommendation was made to expand the pre-surgical data collection timeframe from 0-180 days and expand the post-surgical data collection timeframe from 180-365 days.

With regard to survey administration, it was recommended to define a workflow, which would reduce the instances of multiple surveys being submitted per patient, by determining which one is submitted for reporting. Recommendations were made to evaluate the surveys to ensure that they can be interpreted by all patients with an average reading level of 8th grade or below. This evaluation also included insurance that there is no cultural, ethnic, socioeconomic, religious or gender biasing questions that could influence survey results.

Inclusion Criteria

Most of the commenters selected in the survey that they felt the **Inclusion Criteria** best suits our measure under development. Overall, the inclusion criteria are promising, relevant and align with the denominator criteria.

A recommendation was made to specify whether THA and TKA procedures eligible for this measure could be implemented only in inpatient hospitals or in outpatient and ambulatory surgical center (ASC) settings.

Denominator Exclusion Criteria

Most of the commenters selected in the survey that they felt the **Denominator Exclusion Criteria** best suits our measure under development. Overall, the measure denominator exclusion criteria are appropriate and promising in assessing care goal achievement following THA or TKA.

There were several recommendations, specific to our exclusion criteria:

- Cancer
 - Align specifications with existing measures related to elective primary THA/TKA
 - Consider excluding patients with malignant neoplasm (cancer) of the pelvis, sacrum, coccyx, lower limb, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim
- Severe Cognitive Impairment
 - Align specifications with existing measures related to elective primary THA/TKA
 - Specify how severe cognitive impairment will be determined
 - Reconsider exclusion of patients with severe cognitive impairment
 - Provide rationale for not allowing proxy responses

- Fractures
 - Align specifications with existing measures related to elective primary THA/TKA
 - Align with existing cohort definitions for CMS' elective primary THA and TKA measures which do not require 2 or more fractures
 - Exclude patients with fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields on the index admission claim
- Fractures due to Trauma
 - Align specifications with existing measures related to elective primary THA/TKA
- Hospice
 - Align specifications with existing measures related to elective primary THA/TKA
 - Reconsider exclusion of patients who are/were in hospice care during the measurement period
- Other Exclusion Recommendations
 - Consider excluding patients who expired
 - Consider excluding patients who are transferred in from another acute care facility for THA or TKA
 - Maintain alignment with other measures and concurrent partial hip or knee arthroplasty procedures; concurrent revision, resurfacing, or implanted device/prosthesis removal procedure; mechanical complications coded in the principal discharge diagnosis field on the index admission claim

Preliminary Recommendations

Based on the commenters' suggestions, we conducted additional research on relevant measures to improve alignment (i.e., measure harmonization) across various other PROMs and other relevant measures in the MUC List and NQF database. On March 22nd and 24th, 2021, we reviewed the measure specifications recommendations with our Technical Expert Panel (TEP) members and key stakeholders who provided invaluable guidance as we continued to specify certain aspects of our measure. Based on those meetings, we moved forward to make the following changes at this time to our measure specifications which includes, Measure Numerator Statement, Measure Denominator Statement, and Inclusion and Exclusion Criteria. Due to the length of our responses to each comment, we included those in Public Comment Verbatim table below.

Below are the updated measure specifications that were voted on and endorsed by our TEP members and other key stakeholders following the public comment. Importantly, the following pending any additional qualitative and quantitative assessments and analysis:

Updated Measure Numerator Statement

The total number of patients in the denominator who completed both a pre- and post-surgical care goal achievement (CGA) survey who demonstrated that 75% or more of the patient's expectations from surgery were met or exceeded.

Note: Key change includes defining the PRO-PM threshold of 75% or more of the patient's expectations from surgery were met or exceeded.

Updated Measure Denominator Statement

All adult patients age 18 and older who undergo an elective, primary THA or TKA during the performance period AND who have completed a pre-surgical care goal achievement (CGA) survey 0-90 days before surgery AND a post-surgical CGA survey 90-180 days after surgery.

Note: Key changes include specifying one procedure versus the other by changing 'and/or' to 'or'.

Updated Exclusion Criteria

Patients who meet the following criteria are excluded from the measure:

- A revision THA or TKA procedure
- A conversion THA or TKA procedure
- A fracture of the hip or knee at the time of the THA or TKA
- A malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm that overlaps the data measurement collection period or the THA or TKA procedure
- A simultaneous, bilateral THA or TKA procedure
- Transfer from another acute care facility for the THA or TKA procedure

Note: In meetings with TEP members on March 22nd and 24th, 2021 the following changes were reviewed and agreed upon by the members. Key changes included:

- Specifying one procedure versus the other by changing 'and/or' to 'or' (i.e., THA or TKA)
- Specifying knee instead of lower limb for patients with fractures at the time of the THA or TKA
- Adding patients who underwent conversion THA or TKA to the exclusion criteria
- Adding patients with malignant neoplasms of hip and knee to the exclusion criteria
- Adding patients who underwent a simultaneous bilateral THA or TKA to the exclusion criteria
- Adding patients who transferred from another acute care facility for the THA or TKA to the exclusion criteria
- Removing exclusion criteria for patients with trauma-specific fractures
- Removing exclusion criteria for patients who are/were in hospice care during the measurement period
- Removing exclusion criteria for patients with severe cognitive impairment that overlaps the data measurement collection period or THA or TKA procedure

The changes noted were submitted for the Measure Under Consideration list on May 27th, 2021. The BWH's measure developer team will continue to collect survey responses and update any relevant data for the August 2nd, 2021, NQF submission.

Overall Analysis of the Comments and Recommendations

The BWH's measure developer team appreciates the commenters' considerate input, recommendations, and requests for clarifications about the care goal achievement PRO-PM under development.

Prior to the submission for public comment, we reviewed our measure specifications under development with our TEP members. The items we discussed and decided to submit for comment were the measure numerator and measure denominator statements, and the inclusion and exclusion criteria.

We were pleased to see that we had a wide variety of commenters respond who represented the areas of measure developers, medical associations, healthcare leadership, surgeons, EHR vendors, and healthcare policy makers.

Comments from the public were consistent in most cases with discussions we had with TEP members, patients, patient advocates, providers, payers and other key stakeholders in prior meetings. Specifically, we were pleased to see that most of commenters endorsed our measure specifications and, in some instances, offered constructive suggestions and recommendations. We reviewed the public comments, and along with input from our TEP members and other key stakeholders, made changes to our measure specifications where applicable, to align with other CMS's measures that focus on elective primary THA or TKA.

While the majority of measures related to THA or TKA are clinical functional measures and not measures related to care goal achievement, there were some places where we were able to align our specifications items and in other cases, due to the nature of our measure, we felt it best to make changes that best suited our measure. See the updated measure specifications in the Preliminary Analysis and Recommendations section above.

Some of the commenters stated that it would be useful for them to receive additional information about our engagement level with key stakeholders and how we incorporated their perspectives in the measure development process. These commenters recommended that the care goal achievement criteria consider stakeholders (i.e., patient, caregiver, and patient advocate) feedback. Consistent with this notion, we developed our measure and measure specifications based on a comprehensive qualitative and quantitative testing methods. Specifically, we obtained key stakeholders' input at several points during the measure development process. This qualitative approach consisted of semi-structured interviews and focus groups with patients, care partners, health care providers, payers and experts in the field about the potential value of our measure under development, their perceptions about the measure conceptual framework, key domains, survey items and their recommendation regarding the measure specifications and workflow associated with our new measure. In these interactions we obtained face validity by securing stakeholders opinions on whether the measure is congruent with our intent, feasibility and burden input. Throughout the measure development process, the measure under development and measure specifications were vetted by our TEP members, Steering Committee, measure developers and other stakeholders.

As noted, the updated measure specifications were submitted for the Measure Under Consideration list on May 27th, 2021. The BWH's measure developer team will continue to collect survey responses and update any relevant data for the August 2nd, 2021, NQF submission.

Public Comment Verbatim Report

Comment Number*	Date Posted/Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
	1/12/21	Eugene Nelson, DSc, MPH	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	General Comment - Using PROMs before and after surgery to measure expectations vs perceived outcomes is a good approach for assessing goal achievement.	<u>Response:</u> Thank you for your comment on the overall value of our care goal achievement measure. We agree that this PRO-PM will enable patient-centered care and might help bridge the gap between patients and providers with regard to standardizing care goal achievement. Consistent with this notion, a growing body of evidence supports the importance of identifying and addressing patients' goals and expectations. Nonetheless, previous studies have emphasized that clinicians frequently neglect to solicit information about patients' goals and expectations, tending to underestimate or not recognize them, resulting in unmet expectations and lower satisfaction. Thus, we agree our PRO-PM related to care goal achievement following THA or TKA, will address some of the gaps.
	1/12/21	Eugene Nelson, DSc, MPH	Individual		Care Goal Achievement Following a	Measure Denominator Criteria – Removed/Applied Would	<u>Response:</u> Thank you for your comments. Based on your constructive

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					Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	consider making some modifications. Suggestions shown in CAPITAL LETTERS follows. Adult patients age 18 and older who undergo an elective, primary THA and/or (CONSIDER MAKING THIS JUST "OR" VS AND/OR TO PROVIDE BETTER COMPARABILITY FOR INTERPRETATION) TKA during the performance period AND who have a completed care goal achievement survey within 90 days prior to the date of surgery AND between 90-180 days after surgery. (CONSIDER REDUCING THE WINDOW TO 60 DAYS BEFORE AND AFTER VS 90 DAYS BEFORE AND AFTER)	feedback, we assessed the change from "and/or" to "or" with our key stakeholders and updated the language. Regarding your suggestion to reduce the timeframe to 60 days window before and after surgery, we evaluated the timeframes consideration and are aligned with similar measures, like NQF measure 3559, with regard to the pre-surgical data collection timeframe being 0 to 90 days before surgery. Importantly, our decision about a 90 day window before and after surgery was based on comprehensive qualitative and quantitative assessments of various timeframes.
	1/12/21	Eugene Nelson, DSc, MPH	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria Would consider making some modifications. Suggestions shown in CAPITAL LETTERS follows. Patients who had a revision THA and/or TKA (IS THIS REDUNDANT WITH PRIMARY THA/TKA NOTED IN	<u>Response:</u> Thank you for your comments regarding the denominator exclusion criteria. Regarding your comment related to potential redundancy of revision THA or TKA in the denominator exclusion criteria, other existing measures in the field of orthopedics (i.e.,

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						<p>DENOMINATOR STATEMENT)</p> <p>Patients with a fracture of the hip or lower limb indicating trauma at time of the THA or TKA</p> <p>Patients with severe cognitive impairment (SPECIFY HOW SEVERE COGNITIVE IMPAIRMENT WILL BE DETERMINED) that overlaps the data measurement collection period or THA and/or TKA procedure</p> <p>Patients who are/were in hospice care during the measurement period</p>	<p>primary THA, TKA) included this item in their denominator exclusion criteria. Moreover, the use of the revision CPT code allows for ease of use when reporting out results to CMS/MIPS for reimbursement.</p> <p>Based on your comments, other commenters' suggestions and feedback, along with input from our TEP members and other key stakeholders, at this time, we decided to exclude patients who have a fracture, traumatically-incurred or otherwise, at the time of their THA or TKA.</p> <p>Patients with severe cognitive impairments are being removed from the exclusion criteria given the complexity and variety of definitions as well as a definitive clinical diagnosis at the time of the THA or TKA. Patients who are in hospice during the measurement period are also being removed from the exclusion criteria.</p>
	1/12/21	Eugene Nelson, DSc, MPH	Individual		Care Goal Achievement Following a	Denominator Exclusion Criteria – Cognitive Impairment Suggest	Response: Thank you for your comment about specifying severe

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					Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	specifying how this will be determined.	cognitive impairment. We acknowledge the importance of specifying the criteria. Cognitive impairment was included in the measure specification at the time of the public comment, however, based on your comment, other commenters' suggestions and feedback, along with input from our TEP members and other key stakeholders we are not excluding patients with severe cognitive impairment. Patients with severe cognitive impairment are not being excluded given the complexity and variety of diagnoses as well as a patient having a definitive clinical diagnosis at the time of the THA or TKA.
	1/12/21	Eugene Nelson, DSc, MPH	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Additional Comments The 90 day time window before and after the procedure is quite long. It may be preferable to decrease the time window to 60 days before and 60 days after. For after period, would consider from 120 to 180 days to allow more time for improvement.	<u>Response:</u> Thank you for your comment regarding the measure timeframes of administration. Our timeframes are based on comprehensive qualitative and quantitative assessments that were conducted to support the measure development. Specifically, in multiple

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							interviews and focus groups that we conducted with patients and providers, our timeframe was endorsed and found to be the most appropriate for the concept of care goal achievement. In reviewing your comments and other commenter's suggestions, along with input from our TEP members and other key stakeholders at this time, we are moving forward with the data collection windows of 90 days before surgery and 90-180 days after surgery. We are also aligned with other measures and the 90 days before surgery timeframe.
	1/12/21	William Hamilton, MD, American Association of Hip and Knee Surgeons (AAHKS)	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	General Comment - We understand the importance of measure development and assessing quality. This measure appears quite practical in measuring the outcomes that are most meaningful to patients-pain relief and function improvement. We wonder how these questionnaires differ from well-established measurement tools	<u>Response:</u> Thank you for your comment on the overall value of our care goal achievement measure. Thank you also for your comment addressing differences between our measure and HOOS and KOOS. Our questionnaires differ from the other well-established measures, such as the HOOS and KOOS, as ours assess the patient's main goals and expectations before

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						(HOOS and KOOS) and whether it has been validated.	surgery and the degree to which the expectations were met or exceeded after surgery, whereas the HOOS and KOOS assess patients' clinical function status and not their expectations and goals. Importantly, in multiple interviews and focus groups that we conducted with patients, providers and payers, they saw great value in our care goal achievement measure on top of the existing measures (e.g., HOOS and KOOS). As part of the PRO-PM development process, we are validating the Pre-Op and Post-Op PROMs and the PRO-PM.
	1/12/21	William Hamilton, MD, American Association of Hip and Knee Surgeons (AAHKS)	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria - "The time frame to administer survey is 90 days preop and 90-180 days postop. We recognize these timeframes will be determined after data analysis. However, we would consider expanding the timeframes to capture as many patients as possible. Pre-operatively, 90 days is reasonable,	Response: Thank you for your comment regarding the measure timeframes of survey administration. Our timeframes are based on comprehensive qualitative and quantitative assessments that were conducted to support the measure development. Specifically, in multiple interviews and focus groups that we conducted with patients

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						<p>but would consider expanding to 180. Postoperatively, many patients are still in the midst of their recovery at 90 days (especially total knees), so consideration should be given to starting the interval at 180 days instead of 90 days. Also, consider expanding the postop interval out to 365 days (or more) post op. The challenge of how to administer the surveys, how to collect the data, and how to report this data to CMS will be a tremendous logistical challenge.”</p>	<p>and providers, our proposed timeframe was endorsed and found to be the most appropriate for the concept of care goal achievement. Our timeframes have been endorsed by our key stakeholders, including our TEP members, and are aligned with similar measures, like NQF measure 3559, with regard to the pre-surgical data collection timeframe being 0 to 90 days before surgery.</p> <p>We also acknowledge the challenges of implementing and administering a survey. Currently, we are testing our survey in different electronic and Web-based platforms in a clinical setting and with a patient portal via an EHR. We will use that experience to help shape our final report with regard to best practices, data submission to CMS, and all other areas associated with survey administration.</p>
	1/12/21	William Hamilton, MD, American Association of Hip and Knee	Organization		Care Goal Achievement Following a Total Hip Arthroplasty	Denominator Exclusion Criteria – 1 or More Fractures - We agree that excluding THA/TKA revisions and THA or	<u>Response:</u> Thank you for your comments concerning patient fracture, revision, and conversion exclusions.

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		Surgeons (AAHKS)			(THA) or Total Knee Arthroplasty (TKA)	TKA performed for fractures is appropriate. It is not necessary to require 2 fractures, because most of these procedures would be performed for a single fracture. Consideration should also be given to excluding conversion THA procedures (there is a CPT code to identify these cases) and conversion TKA procedures (there is no code to identify these procedures). Providers or centers that perform higher percentage of "conversions" could be biased against based on the differential outcomes of these cases.	Based on your comment, other commenter's suggestions and feedback, along with input from our TEP members and other key stakeholders, we updated our exclusion criteria and at this time, we are excluding patients with 1 fracture, patients with revisions, and patients with conversion THA or TKA.
	1/12/21	William Hamilton, MD, American Association of Hip and Knee Surgeons (AAHKS)	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – Cognitive Impairment Specificity - Regarding the question on the specifics of cognitive impairment, we would recommend adding specific diagnoses parenthetically (e.g., dementia).	<u>Response:</u> Thank you for your comments about specifying severe cognitive impairment. We acknowledge the importance of specifying the criteria. Based on your comment, other commenter's suggestions and feedback, along with input from our TEP members and other key stakeholders, we updated our exclusion criteria and are not

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							excluding patients with severe cognitive impairment. Patients with severe cognitive impairments are not being excluded given the complexity and variety of diagnoses as well as a patient not having a definitive clinical diagnosis at the time of the THA or TKA.
	1/12/21	William Hamilton, MD, American Association of Hip and Knee Surgeons (AAHKS)	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Additional Comments – Burden - We would endorse consideration of developing an electronic means of administering the survey that is web based and simple. This would allow the score to be recorded by the provider but also directly reported to CMS. This may also unburden the provider from collecting the data in the office. Using enhanced technology for data collection may exclude patients with poor access to devices or wi-fi to complete the questionnaire, but this is evolving over time, so most patients utilize a smartphone.	<u>Response:</u> Thank you for your comment regarding survey administration. Consistent with your suggestion, our plan for the measure is primarily a web-based administration that will work with an EHR, which is how we are testing currently, or a third-party software vendor. Furthermore, we are testing our survey in different electronic and Web-based platforms in a clinical setting and with a patient portal. In both cases, the survey can be completed via desktop, laptop, iPad, and smart phone. The survey can also be completed via a paper format or over the phone for those clinician-groups without access to an EHR.

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	1/12/21	William Hamilton, MD, American Association of Hip and Knee Surgeons (AAHKS)	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	<p>Additional Comments – Survey Interpretation - We recommend that the surveys be evaluated to ensure that they can be interpreted by all patients. The survey should read so it would require an average reading level of 8th grade or below.</p> <p>We recommend that the survey be evaluated to insure there is no cultural, ethnic, socioeconomic, religious or gender biasing questions that could influence survey results.</p>	Response: Thank you for your comments regarding survey literacy and bias. We acknowledge the importance of readability and literacy when it comes to measure development. To address this, we conducted multiple interviews and focus groups with a variety of patients to get their feedback about our survey. Specifically, we conducted cognitive testing interviews with patients, and they reported that the survey questions were clear, relevant, appropriate, and easy to understand and answer. Importantly, the patients that we conducted our interviews and focus groups with were from diverse socioeconomic, racial/ethnic backgrounds and we had an even gender distribution.
	1/12/21	William Hamilton, MD, American Association of Hip and Knee Surgeons (AAHKS)	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee	Additional Comments – Survey Questions - Question 1. Many patients undergoing THA/TKA have no pain at rest. Question 1 may not be measuring what is intended to be measured	Response: Thank you for your comment concerning the survey 'pain at rest' question. We conducted multiple interviews and focus groups with a variety of patients, providers and

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					Arthroplasty (TKA)	or may bias towards physicians that care for patients at the extreme end of disease severity.”	other key stakeholders to get their feedback about the survey items/questions; all of which led to the decision about the inclusion of the ‘pain at rest’ question. Moreover, patients and providers saw great value in this specific question. Importantly, our qualitative findings regarding the importance of this question were supported by our quantitative testing (i.e., analysis of patients’ responses to this question).
	1/13/21	Carolyn Kerrigan, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	General Comment My only concern is that all PRE questions ask about patient expectations rather than their goals. I see this as an expectations PRO not as a goal achievement PRO.	<u>Response:</u> Thank you for your comment regarding the pre-op survey questions. We acknowledge the complexity of the concept of goals and expectations and therefore we conducted an exhaustive literature review, qualitative interviews and focus groups with patients, providers, and measure experts. In addition, we consulted with patient-centered care and patient experience experts about this issue. Based on our findings,

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							we decided that the language of 'expectations' best represents our intentions and the measure under development (i.e., Care Goal Achievement PRO-PM).
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	General Comment - Capturing and evaluating patient's expectations before and after procedures are important to improve patient's care quality.	<u>Response:</u> Thank you for your comment on the overall value of our care goal achievement measure. We do agree that this PRO-PM will enable patient-centered care and might help bridge the gap between patients and providers with regard to standardizing care goal achievement.
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Measure Numerator Statement - Although the information shared in the MIF is limited, it aligns with the measure.	<u>Response:</u> Thank you for your comment regarding our measure numerator statement.
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Measure Denominator Statement - It aligns with the measure. The MIF mentions that the denominator statement will be further defined based on the quantitative and qualitative testing data/information and analysis, it will help to	<u>Response:</u> Thank you for your comments about the denominator statement. With regard to the type of testing data, we are testing our surveys in different electronic and Web-based platforms in a clinical setting and with a patient portal via an

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						know more details on what type of testing data is planned as patient's survey are not often collected before/after procedures (current state).	EHR, whereby surveys are scheduled for patients prior to surgery and post-surgery. This allows us to capture the data needed to test the surveys and develop the PRO-PM. Additional information about our testing methods and findings will be presented in our final Testing Summary Report.
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Inclusion Criteria - If the inclusion criteria same as denominator criteria, it aligns. MIF does not include much detail.	<u>Response:</u> Thank you for your comment regarding the measure inclusion criteria. While the MIF included limited details at the time of our Public Comment posting, our inclusion criteria aligns well with other existing measures as well as our quantitative and qualitative findings.
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria - Current exclusions seem appropriate as will impact the post-procedure patient outcomes.	<u>Response:</u> Thank you for your comments regarding the measure denominator exclusion criteria. Based on commenter's suggestions and feedback, along with input from our TEP members and other key stakeholders, we updated our exclusion criteria. We aligned our denominator exclusion criteria with other existing

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
							orthopedic measures, where applicable
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion – Removed/Applied - Consider adding patient expired as exclusion criteria.	<u>Response:</u> Thank you for your comment regarding expired patients as exclusion criteria. This is a thoughtful consideration but given that our PRO-PM score is derived from the patient completing both the pre- and post-surgical survey, by default, including them is not necessary.
	1/14/21	Isbelia Briceno, Cerner Corporation	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – Cognitive Impairment Specificity - We agree with the inclusion of specific 'chronic' disorders that are known to cause cognitive impairment for extended period of time. Otherwise, it will be open to interpretation what 'severe cognitive impairment' means.	<u>Response:</u> Thank you for your comment about specifying severe cognitive impairment. We acknowledge the importance of specifying the criteria. Based on your comment, other commenter's suggestions and feedback, along with input from our TEP members and other key stakeholders, we updated our exclusion criteria and are not excluding patients with severe cognitive impairment.
	1/15/21	Ariane Marelli, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total	General Comment - Very helpful. Excellent measure.	<u>Response:</u> Thank you for your comment on the overall value of our care goal achievement measure. We agree that this PRO-PM will enable

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					Knee Arthroplasty (TKA)		patient-centered care and might help bridge the gap between patients and providers with regard to standardizing care goal achievement.
	1/15/21	Ariane Marelli, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Measure Denominator Statement - Well designed.	<u>Response:</u> Thank you for your positive feedback about the denominator statement for our Care Goal Achievement PRO-PM.
	1/15/21	Ariane Marelli, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Measure Numerator Statement - Relevant numerator.	<u>Response:</u> Thank you for your comment regarding our measure numerator statement for our Care Goal Achievement PRO-PM.
	1/15/21	Ariane Marelli, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Inclusion Criteria - Pertinent and precise.	<u>Response:</u> Thank you for your positive feedback regarding the measure inclusion criteria for our Care Goal Achievement PRO-PM.
	1/15/21	Ariane Marelli, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total	Additional Comments - Excellent work.	<u>Response:</u> Thank you for your positive feedback – we appreciate it.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
					Knee Arthroplasty (TKA)		
	1/15/21	Howard Bregman, MD, MS, Epic	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – 1 or More Fractures - I am not expressing an opinion on this question. Ideally the survey would have allowed no opinion to be submitted.	<u>Response:</u> Thank you for your comment.
	1/15/21	Howard Bregman, MD, MS, Epic	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – 1 or More Fractures - We recommend aligning with existing cohort definitions for CMS' elective primary THA/TKA measures which do not require 2 or more fractures.	<u>Response:</u> Thank you for your comments regarding the fracture denominator exclusion criteria. At this time, we are aligned with other measures and are excluding patients with 1 or more fractures.
	1/15/21	Howard Bregman, MD, MS, Epic	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – Cognitive Impairment Specificity - I am not sure how you can avoid specifying dementia, since cognitive impairment is going to be defined as a diagnosis, and therefore dementia will have to be included.	<u>Response:</u> Thank you for your comment about specifying severe cognitive impairment. We acknowledge the importance of specifying the criteria. Based on your comment, other commenter's suggestions and feedback, along with input from our TEP members and other key stakeholders, we updated our exclusion criteria and are not excluding patients with

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
							severe cognitive impairment.
	1/15/21	Howard Bregman, MD, MS, Epic	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Additional Comments - I think the biggest challenge will be dealing with multiple surveys being submitted, meaning there may be multiple post-procedure scores that are recorded. You will have to handle this situation in your measure, either by defining the first result or the highest result, or some other criteria.	<u>Response:</u> Thank you for your comments about survey administration and acknowledge the challenges. We tested our survey in different electronic and Web-based platforms in a clinical setting and with a patient portal via an EHR and were able to use that data to review the issue of multiple survey submissions. We will include our findings in our final report with regard to best practices for data submission to CMS, and all other areas associated with survey administration.
	1/15/21	Rachel Brodie	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	General Comments - Goal achievement is not often measured in a standardized and meaningful way. The goal attainment scale is a valuable metric as it allows patients to fill in the blank with their personal goal, and then later assess whether that goal was achieved. However, since the scope of the goals could vary so immensely, this complicates standardized measurement. This PRO-	<u>Response:</u> Thank you for your detailed comments on the overall value of our care goal achievement measure. We do agree that this PRO-PM will enable patient-centered care and might help bridge the gap between patients and providers with regard to standardizing care goal achievement. Consistent with this notion, a growing body of evidence supports the importance of identifying

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						PM under development enables standardized measurement of specific outcomes/care goal achievement and is quite unique.	and addressing patients' goals and expectations. Nonetheless, previous studies have emphasized that clinicians frequently neglect to solicit information about patients' goals and expectations, tending to underestimate or not recognize them, resulting in unmet expectations and lower satisfaction. Thus, we agree that our PRO-PM under development related to care goal achievement following THA or TKA will help standardize this area of outcomes.
	1/15/21	Rachel Brodie	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Inclusion Criteria - Cannot comment on the clinical relevance of the inclusion criteria, exclusion criteria, etc.	<u>Response:</u> Thank you for your comment regarding the measure inclusion criteria for our Care Goal Achievement PRO-PM. While the MIF included limited details at the time of the Public Comment posting, our inclusion criteria and exclusion criteria aligns well with other existing measures as well as our quantitative and qualitative findings.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty	Measure Numerator Statement - From the materials provided for public comment, the measure numerator	<u>Response:</u> Thank you for your comment regarding our measure numerator statement.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
					(THA) or Total Knee Arthroplasty (TKA)	statement appears to have promise in assessing care goal achievement following THA and/or TKA procedures. We look forward to understanding more about how the numerator will be calculated.	
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Numerator Criteria – Removed or Applied - From the materials provided for public comment, the measure appears to have promise in assessing care goal achievement following primary elective THA and/or TKA procedures. We recognize the importance of asking patients about their care goals and assessing their satisfaction with their surgery. A measure of care goal achievement could help patients assess clinician and clinician group quality and would supplement the existing suite of clinician and clinician group-level THA/TKA outcome measures.	<u>Response:</u> Thank you for your detailed comment regarding the measure numerator criteria and the overall value of our care goal achievement measure. We do agree that this PRO-PM will enable patient-centered care and might help bridge the gap between patients and providers with regard to standardizing care goal achievement. Consistent with this notion, a growing body of evidence supports the importance of identifying and addressing patients' goals and expectations. Nonetheless, previous studies have emphasized that clinicians frequently neglect to solicit information about patients' goals and expectations, tending to underestimate or not recognize them, resulting

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							in unmet expectations and lower satisfaction. Thus, we agree that our PRO-PM related to care goal achievement following THA or TKA will help standardize this area of outcomes.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	<p>Measure Denominator Statement - From the materials provided for public comment, it appears that the post-operative survey would be administered between 90-180 days after the procedure.</p> <p>Under contract with CMS, CORE is developing a measure to assess substantial clinical improvement in patient outcomes following primary elective THA/TKA for clinicians and clinician groups (MIPS THA/TKA PRO-PM). The measure is aligned with the existing clinician-level functional status elective primary THA and TKA process measures developed to incentivize the data collection for this outcome measure as well as a hospital-level PRO-PM assessing substantial clinical improvement</p>	<p><u>Response:</u> Thank you for your detailed comments concerning measure alignment with respect to the measure's data collection timeframes. We acknowledge the importance of alignment of our new PRO-PM with existing PROMs/PRO-PMs for THA/TKA. Specifically, we recognize the importance of being attentive to the patient additional burden with respect to filling out too many surveys in different timeframes and providers additional burden with respect to administer and track responses at different timeframes. Consistent with this notion, we conducted exhaustive environmental scan and literature review of relevant existing measures in the field of orthopedics, as well as qualitative and</p>

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						<p>following elective primary THA/TKA (hospital-level THA/TKA PRO-PM) recently endorsed by NQF. We recommend the pre- and post-operative data collection periods be aligned with these measures as appropriate. When discussing PRO-PMs with patients, they have noted concern on being asked to fill out too many surveys and providers have noted concern on burden of survey administration, tracking, and data submission. We recommend consideration of these preoperative and postoperative collection timeframes to align the care goal achievement outcome assessment periods with other THA/TKA measure outcomes and counter the additional burden to administer/complete/track responses at different timeframes. In addition, because the items included in the care achievement surveys and the HOOS, JR and KOOS, JR contain overlapping concepts, we recommend explanation to patients and providers</p>	<p>quantitative assessments of various timeframes. Specifically, in order to assess the measure specification, including the timeframes of the survey administration, we conducted multiple semi-structured interviews and focus groups with patients, caregivers, providers, payers and experts in the field. One of the main topics we discussed with these stakeholders was the appropriate timeframes for this distinctive measure that focuses on care goal achievement with the notion that we should minimize patient and provider burden. Based on their opinions, we concluded that the best timeframe to collect information about patient's goals and expectations is 90-180 days after the procedure. Importantly, our qualitative findings regarding the timeframes were supported by our quantitative testing. In order to assess the potential additional burden to patients, we also conducted cognitive testing interviews with patients where we tested</p>

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						about the importance of both sets of surveys and how they will be used.	<p>the time of completion of our pre-operative 8-item survey and post-operative 9-item survey. In this testing, patients completed each of our surveys in about 2 minutes and reported that the survey questions were easy to answer and did not require significant efforts.</p> <p>In addition, the CGA PROMs/PRO-PM have been fully operationalized in a real use case scenario, into Epic, an electronic health record (EHR) system at Mass General Brigham (MGB). Through engagement with our stakeholders, including the PROMs implementation team at MGB, the development team confirmed that this PRO-PM did not result in increased document and/or processes' burden for clinicians. Thus, our findings show there has been not undue burden on patients or providers and that the measure itself has been very easy to incorporate into the process of care at Mass General Brigham.</p>

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							Based on all the above findings, it seems that our new questionnaires differ from other measures used in orthopedics, as ours assess the patient's main goals and expectations before surgery and the degree to which the expectations were addressed after surgery, and not their functional status, pain level or any other clinical parameter. Finally, we appreciate your recommendation for an explanation about the importance of both sets of surveys and how that information will be used.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Measure Numerator Criteria – Removed/Applied - From the materials provided for public comment it appears that the care goal achievement score and criteria will be defined based on quantitative and qualitative testing data and analysis. To develop a usable measure, the care goal achievement criteria should consider patient, caregiver, and patient advocate feedback. To provide further input, we would require more	<u>Response:</u> Thank you for your detailed comment regarding the measure numerator criteria. We acknowledge the importance of identifying and incorporating the perspectives of key stakeholders throughout the measure development process. Consistent with this notion, we conducted multiple semi-structured interviews and focus groups with patients, caregivers, providers, payers and experts in the field related to our

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						detailed information about the measure specifications and definitions of the measure numerator and denominator.	measure under development. Moreover, we engaged patient advisors and received their input throughout the various stages of the measure development process; all of which contributed to the development of the measure numerator statement and the other measure specifications.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Measure Denominator Criteria – Removed/Applied - Once more detailed information is available, we are happy to provide input. Again, we recommend aligning numerator and denominator definitions with existing measures to minimize provider burden and confusion as appropriate.	<u>Response:</u> Thank you for your comment about the measure denominator criteria. As mentioned in one of the previous comments, we acknowledge the importance of alignment of our new PRO-PM with existing measures to minimize additional patient and provider burden. Consistently, we conducted exhaustive environmental scans and literature reviews of relevant existing measures in the field of orthopedics as well as comprehensive qualitative and quantitative assessments of the measure denominator criteria; all of which led to the

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							decision about the denominator criteria.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Inclusion Criteria - From the materials provided for public comment, the measure inclusion criteria appear to have promise in assessing care goal achievement following THA and/or TKA procedures. It is unclear from the materials whether the THA/TKA procedures eligible for this measure include only inpatient hospital procedures or procedures that occur in outpatient or ASC settings. Given patients may not have input on whether they will undergo a THA/TKA in the hospital setting as an inpatient or outpatient, stakeholders have expressed support for measuring all THA/TKA procedures regardless of setting be included in the measure.	<u>Response:</u> Thank you for your constructive comment regarding the setting to be included in the measure. Our measure was specifically developed for eligible clinicians/clinician-groups participating in MIPS. While this measure was not submitted for consideration in the ASC program at this time, it could be adapted for use in those settings.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Inclusion Criteria – Removed/Applied - Once more detailed information is available, we are happy to provide input. Again, we recommend aligning numerator and denominator definitions with existing measures to	<u>Response:</u> Thank you for your comment about the measure inclusion criteria. As mentioned in one of the previous comments, we acknowledge the importance of alignment of our new PRO-PM with

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						minimize provider burden and confusion as appropriate.	existing measures to minimize additional patient and provider burden and have done so where applicable as noted in the summary. Consistently, we conducted exhaustive environmental scan and literature review of relevant existing measures in the field of orthopedics as well as comprehensive qualitative and quantitative assessments of measure inclusion criteria; all of which led to the decision about the inclusion criteria.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria - From the materials provided for public comment, the measure denominator exclusion criteria appear to have promise in assessing care goal achievement following THA and/or TKA procedures. Once more detailed information is available, we are happy to provide input. Again, we recommend aligning numerator and denominator definitions with existing measures to minimize provider burden	<u>Response:</u> Thank you for your comments regarding the measure denominator exclusion criteria. We have aligned our denominator exclusion criteria with other orthopedic measures and are confident with their contribution to our measure. Your recommendations regarding alignment were taken into consideration to minimize any potential patient and provider burden.

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						and confusion as appropriate.	
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	<p>Denominator Exclusion – Removed/Applied - Given this measure focuses on elective, primary THA/TKA, the measure exclusion criteria to remove patients who are/were in hospice during the measurement period may not be needed given hospice patients are unlikely to undergo elective, primary THA/TKA.</p> <p>We would like more information about the rationale for excluding patients with dementia and how these patients will be identified. In addition, has the developer considered allowing proxy responses and what is the rationale for their decision? We recommend consideration of alignment across the care achievement cohort criteria with other quality measures focused on the elective, primary THA/TKAs. Specifically, the MIPS THA/TKA complication measure, the hospital-level THA/TKA complication, readmission, and</p>	<p>Response: Thank you for your comments regarding denominator exclusion criteria. Based on your comment and other commenters' suggestions and feedback from our TEP members, we updated our exclusion criteria and at this time, have removed patients who are/were in hospice from the exclusion criteria.</p> <p>Regarding proxy responses, we also discussed this with key stakeholders (e.g., patients and providers), including TEP members, who all had concerns with someone else responding on behalf of a patient's expectations/goals of their THA/TKA, as this concept of expectations and goals is very subjective. Therefore, at this time we don't allow proxy responses.</p> <p>While we aligned these criteria based on other relevant orthopedic measures under development and endorsed by NQF, we reviewed the criteria</p>

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						<p>payment measures, and the recently NQF-endorsed hospital-level THA/TKA PRO-PM focus on elective primary THA/TKA procedures defined as procedures without fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields on the index admission claim; concurrent partial hip or knee arthroplasty procedures; concurrent revision, resurfacing, or implanted device/prosthesis removal procedure; mechanical complications coded in the principal discharge diagnosis field on the index admission claim; malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim; and transfers from another acute care facility for THA/TKA. Alignment of the measure cohort criteria with other THA/TKA quality measures will help</p>	<p>further based on your suggestions, as well as the other measures you mentioned, to see if there can be more concise alignment with other measures. In accordance, we aligned additional exclusion criteria with the measures you mentioned.</p>

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						support CMS's goal of measure alignment and allow for patient understanding of the measure results. Importantly, alignment of the cohort for care goal achievement measure and other THA/TKA PRO-PMs will support ease of patient selection for PRO data collection.	
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – Trauma - This appears to align with existing cohort definitions for CMS' elective primary THA/TKA measures. We recommend the final specifications align to the extent feasible with existing measures to minimize provider burden and confusion.	<u>Response:</u> Thank you for your comments regarding the trauma denominator exclusion criteria. We consciously aligned our denominator exclusion criteria with other orthopedic measures we researched in CMIT and other sources. Upon further review with key stakeholders, at this time, we are excluding patients who have a fracture/fractures, traumatically-incurred or otherwise, at the time of their THA or TKA. Thus, we are excluding patients who have a fracture of the hip or knee at the time of the THA or TKA.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty	Denominator Exclusion Criteria – 1 or More Fractures - We recommend aligning with existing cohort definitions	<u>Response:</u> Thank you for your comments regarding the fracture denominator exclusion criteria. Based on your

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					(THA) or Total Knee Arthroplasty (TKA)	for CMS' elective primary THA/TKA measures which do not require 2 or more fractures.	comment, other commenter's suggestions and feedback, along with input from our TEP members and other key stakeholders, we updated our exclusion criteria and at this time, we are aligning with other measures and are excluding patients with 1 or more fractures.
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Denominator Exclusion Criteria – Cognitive Impairment - This exclusion criterion is somewhat vague, as short-term delirium episodes could lead to exclusion of patients from measurement that are fully capable of responding to the surveys. In addition, if a severely cognitively impaired person is undergoing an elective surgery such as THA/TKA, we believe it is important to include them in performance measurement. Has the developer considered proxy responses for this measure?	<u>Response:</u> Thank you for your comments regarding the cognitive impairment denominator exclusion criteria. We appreciate your input about short-term delirium episodes. We discussed this and proxy responses with patients, providers and other key stakeholders, including TEP members, who all had concerns with someone else responding on behalf of a patient's expectations/goals of their THA/TKA, as this concept of expectations and goals is very subjective. While we aligned these criteria based on other orthopedic measures under development and endorsed by NQF, we

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							<p>reviewed other measures and conferred with key stakeholders and at this time, are not excluding patients with severe cognitive impairment or utilizing proxy responses.</p> <p>In addition, patients with severe cognitive impairments are being removed from the exclusion criteria given the complexity and variety of definitions as well as a definitive clinical diagnosis at the time of the THA or TKA.</p>
	1/15/21	Lisa Suter, MD, Yale-CORE	Organization		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	<p>Additional Comments - We thank the BWH team for the opportunity to comment. We recognize that providers may be incentivized to not perform surgeries for patients with too high expectations as an unintended consequence of this measure if it is publicly reported, but we support the measure concept as complementary to an actual measure of PROs. We encourage the developer to perform careful assessment of any risk adjustment, particularly for the unintended consequence of worsening disparities.</p>	<p><u>Response:</u> Thank you for your comments regarding risk adjustment. We worked with our psychometrician and other measure developers to identify areas where risk adjustment may be needed. At this time, the risk adjustment areas this measure calculated for are age, gender, and BMI, which are areas typically adjusted for in orthopedics, particularly THA and TKA.</p>

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						While the pre-operative information about patient expectations will provide important foundation for shared decision-making discussions about surgery, the post-operative PROM and the interpretation of whether expectations were met could be influenced by a range of social risk factors that may be difficult to measure. Further, risk adjusting for some social risk factors or other demographic information could lead to worsening care for at risk populations and increase disparities.	
	1/15/21	Katherine Ast, MSW, LCSW	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	General Comment - A very interesting measure concept. Palliative care has been trying to capture goal-concordant care for years. I think this measure has potential to move the concept along and improve communication and shared-decision making among patients and their providers.	<u>Response:</u> Thank you for your comment on the overall value of our care goal achievement measure. We do agree that this PRO-PM will enable patient-centered care and might help bridge the gap between patients and providers with regard to standardizing care goal achievement. Consistent with this notion, a growing body of evidence supports the importance of identifying and addressing patients' goals and expectations. Nonetheless, previous

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							studies have emphasized that clinicians frequently neglect to solicit information about patients' goals and expectations, tending to underestimate or not recognize them, resulting in unmet expectations and lower satisfaction. Thus, we agree our PRO-PM related to care goal achievement following THA or TKA, will address some of the gaps mentioned.
	1/16/21	Eyal Zimlichman, MD	Individual		Care Goal Achievement Following a Total Hip Arthroplasty (THA) or Total Knee Arthroplasty (TKA)	Additional Comments - I agree with the defined measure and the criteria set. This has the potential to become an important milestone in assessing patient expectations and tying expectations to outcomes.	Response: Thank you for your comment regarding our defined measure and criteria. We have developed a well-rounded measure that assesses the patient's main goals and expectations before surgery, and the degree to which the expectations were addressed after surgery. We agree with your statement that the new measure as the potential to become an important milestone in assessing patient expectations and tying expectations to outcomes.

*Optional

All comments in the table appear as they were received and have not been edited for spelling, punctuation, grammar, or any other reasons.